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MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Disease Prevention Claim for Soy Protein and Coronary Heart Disease
Docket No. 98P-0683
64 Fed. Reg. 45932 (August 23, 1999)

The Grocery Manufacturers of America (GMA) is the world's largest association of food, beverage, and consumer brand companies. With consumer sales more than $450 billion, GMA member companies employ more than 2.5 million workers in all 50 states. GMA speaks for food and consumer brand manufacturers at the state, federal, and international levels on legislative and regulatory issues. GMA and its member companies have a continuing interest in the use of truthful and nonmisleading disease prevention claims, including claims about the relationship between soy protein and coronary heart disease.

Executive Summary

In these comments, GMA makes the following three points. First, the only issue under the Federal Food, Drug, and Cosmetic Act (FD&C Act) is whether a disease prevention claim on the relationship between soy protein and coronary heart disease meets the statutory standard of "significant scientific agreement." If this standard is met, FDA has no discretion to disapprove the claim.

Second, as FDA itself repeatedly testified before Congress, the agency has no statutory authority to require the inspection of food industry records. The food industry has the

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right to determine whether voluntarily to disclose records to FDA or to decline such disclosure. FDA cannot condition use of a right under both the Constitution and the FD&C Act to make a documented disease prevention claim on the unlawful requirement that a food manufacturer give up its statutory right to retain its records as confidential. This would amount to what a recent United States District Court decision has characterized as "a kind of constitutional blackmail." Thus, FDA cannot lawfully limit use of a soy protein/coronary heart disease claim to foods that use soy as the sole source of protein or to companies that allow records inspection.

Third, FDA should promptly promulgate the final regulation authorizing the disease prevention claim on the relationship between soy protein and coronary heart disease and should rely upon three means of enforcement. As FDA has itself on many occasions pointed out, companies do routinely allow FDA to inspect company records, on a voluntary basis, where good reason is shown, and this will continue to occur in the future. Companies also routinely conduct analyses of competitive products, often using proprietary methodology of the type identified by FDA in its Federal Register notice, and can be expected to bring to FDA's attention any violations of the regulation. Finally, FDA can and should lead a broad effort involving USDA, agricultural research groups, academia, the food industry, and FDA scientists, to develop and validate any additional analytical methods needed for enforcement of this regulation. FDA cannot, however, lawfully hold the regulation hostage pending development of this methodology.

I. The Soy Protein/Coronary Heart Disease Claim Should Immediately Be Approved

Sections 403(r)(1)(B) and 403(r)(3) set forth the requirements for FDA approval through promulgation of a regulation for any claim relating a food to a disease. Specifically, Section 403(r)(3)(B)(i) states that FDA "shall" promulgate such a regulation upon a

determination that it is supported by "significant scientific agreement." Accordingly, once FDA has made the determination that significant scientific agreement supports a disease prevention claim -- as FDA clearly did in the preamble to the proposed regulation in 63 Fed. Reg. 62977 (November 1, 1998) -- the agency has no discretionary authority to deny the use of that claim. Indeed, as the recent decision in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), makes clear, denial of a claim under these circumstances would not only be unlawful under the FD&C Act but also unconstitutional under the First Amendment.

II. The FD&C Act Contains No Authority For FDA to Require Records Inspection, and FDA Cannot Condition the Use of a Documented Disease Prevention Claim Upon Giving Up the Right to Retain Business Records As Confidential

The FD&C Act does not provide FDA statutory authority to inspect the records of food manufacturers. FDA explicitly recognized that fact when the current statutory provision in Section 704 was enacted in 1953 and it has repeatedly stated that position to Congress throughout the intervening five decades.

In February 1996, FDA proposed to establish records requirements for nutrient descriptors and disease prevention claims by regulation.[1] GMA submitted substantial comments objecting to the proposed regulation, documenting forty years of FDA statements that the agency has no records inspection authority for the food industry. A copy of those comments is attached to and made a part of these comments. To summarize, FDA has at no time in the past four decades asserted records inspection authority with respect to the food industry, and has repeatedly informed Congress that it has no such authority. No judicial decision is contrary to

[1] 61 Fed. Reg. 3885 (February 2, 1996).

that position. Accordingly, FDA cannot simply assert, by regulation, the authority to inspect food company records when that authority has been definitively and repeatedly denied by Congress.

In this particular proposal, FDA advances the need for records inspection on the basis of ease of enforcement. This is the identical ground relied upon in the April 1996 proposal. The fact remains, however, that FDA has presented this rationale to Congress on numerous occasions over the past forty years, and Congress has on every occasion rejected it. Ease of enforcement is not a justification for overturning a statute.

Nor is there any authority under the Nutrition Labeling and Education Act of 1990 for FDA to condition use of a documented disease prevention claim upon records inspection or, indeed, giving up any other statutory rights. Congress unambiguously required FDA to approve a disease prevention claim if it is based upon significant scientific agreement. No other conditions relating to enforcement were included in the 1990 statute or in any other part of the FD&C Act.

As has been made clear in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), the food industry has a constitutional right under the First Amendment to make truthful and nonmisleading disease prevention claims. Nothing in the Constitution authorizes FDA to deny protected speech on the basis of ease of enforcement. As the court has pointed out in the recent case of Washington Legal Foundation v. Henney, _____ F. Supp. 2d. ____ (D.D.C. 1999):

> "The First Amendment is premised upon the idea that people do not need the government's permission to engage in truthful, nonmisleading speech about lawful activity." (Slip Op. at 8.)

That court went on to point out that only speech that is demonstrably false or misleading is prohibited under the First Amendment:

> "First, 'potentially misleading' speech is not proscribable under the First Amendment. The FDA may not restrict speech based on its perception that the speech could, may, or might mislead. Rather, for the protection of the First Amendment to fall away, the government must demonstrate that the restricted speech, by nature, is more likely to mislead than to inform, a demonstration which the defendants have not made here." (Slip Op. at 9, citations omitted.)

Moreover, that court pointed out that the speech that FDA sought to prohibit in that case (information about unapproved uses of approved new drugs) could not possibly be regarded as misleading because the same information was allowed to be disseminated under other circumstances. (Slip Op. at 9-10.)

The identical situation occurs here. The FDA proposal makes clear that the soy protein/coronary heart disease claim is in fact documented and truthful and in no way misleading. Accordingly, it is entitled to First Amendment protection. The potential that some food manufacturer might use the claim without adequate documentation, and without the ability of FDA to enforce the requirements using records inspection, is simply not sufficient to deny that First Amendment right. As the court in the Washington Legal Foundation case stated, conditioning the First Amendment right upon giving up the right to maintain company records as confidential "amounts to a kind of constitutional blackmail." (Slip Op. at 14.) FDA therefore cannot lawfully limit the soy protein/coronary heart disease claim to foods that use soy as the sole source of protein or to companies that permit inspection of records.

III. FDA Can Enforce This Disease Prevention Claim in the Same Way It Enforces Other Food Labeling Claims.

FDA does not have, and never has had, the statutory authority to require food manufacturers to submit their business records to FDA inspection. Nonetheless, FDA has enforced federal food law requirements, without such authority, for more than 90 years. In numerous instances, food manufacturers make claims in product labeling that cannot easily be verified by FDA because they do not have access to the food manufacturer's records. For nine decades, however, FDA has successfully enforced the law under these circumstances using a variety of mechanisms.

First, the food industry has routinely provided specific records to FDA, on a voluntary basis, where FDA has requested particular records for a specified purpose and provided adequate justification. FDA officials have often recognized that the industry cooperates daily with the agency on this basis. The lack of FDA authority to require records inspection should thus not obscure the fact that FDA does receive food industry records on a voluntary basis every day of the week. Neither the proposed regulation nor any other documentation prepared by FDA has demonstrated that the voluntary provision of such records, on the basis of adequate justification, is inadequate to provide reasonable enforcement of the disease prevention provisions of the FDA regulations.

Second, companies routinely conduct analyses of competitive products in order to determine that the entire industry is complying with the applicable regulatory requirements. Many of these analyses are conducted using the type of proprietary methodology that FDA acknowledged in the preamble to this regulation (page 45933). Where deviations from FDA

regulations are discovered, the food industry regularly provides that information to FDA. It has been estimated that up to ninety percent of FDA enforcement action is based upon trade information provided in this way. Again, nothing in the FDA preamble or in any other documentation suggests that this, along with the voluntary provision of company records, is insufficient to result in reasonable enforcement of the disease prevention provisions of the FDA regulations.

Finally, FDA has long exerted leadership in the development and validation of analytical methodology for use in enforcing federal food laws and regulations. Even before enactment of the Federal Food and Drugs Act of 1906, FDA pioneered the establishment of the Association of Analytical Chemists (AOAC), which today remains the authoritative source for analytical methodology. FDA can readily establish its traditional leadership in this field, with the cooperation of USDA, other agricultural research groups, the food industry itself, and interested academic scientists, to develop and validate any additional analytical methods needed to enforce the provisions in the statute and FDA regulations governing disease prevention claims.

IV. Conclusion.

For the reasons set forth above, FDA should withdraw its proposed regulation of August 23, 1999, and should proceed to promulgate a final disease prevention claim for soy protein and coronary heart disease as proposed on November 10, 1998.

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